

## Office Action Summary

Application No.

10/673,650

Applicant(s)

VAN ERP ET AL.

Examiner

Bhisma Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Specification***

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the proximal ends of the inner and outer tubular bodies being sealed to the hypotube at a point defined proximal to a transition between the intermediate and distal portions of the hypotube.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5, 6, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (U.S. Patent No. 5,217,482) in view of Happ et al (U.S. Patent No. 6,575,958).

In Figure 5, Keith shows a rapid-exchange catheter comprising a stainless steel hypotube (22B), an inner tubular body (80B), and an outer tubular body (82B). The hypotube has a proximal tubular portion, an intermediate tubular portion (117) having a longitudinal indentation (72B), and a distal portion (74B). The proximal portion of the hypotube is cylindrical. The distal portion of the hypotube has an arcuate cross-section

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(72B) and extends into the outer tubular body. In lines 37-65 of column 8, Keith teaches that it is desirable to provide a transition in flexibility between the tubular portions of the hypotube to the inner and outer tubular bodies and also teaches that it is the intermediate tubular portion and the distal portion of the hypotube which provide this transition in flexibility. The inner tubular body has a proximal guidewire port, a distal guidewire port, and a guidewire lumen (52) which extends between the ports. In Figure 5, Keith shows the proximal end of the inner tubular body (80B) and the proximal end of the outer tubular body (82B) being affixed together and sealed to the hypotube (22B). In lines 37-62 of column 7, Keith teaches sealing the proximal end of the outer tubular portion (82) to the hypotube (66) with a single seal and sealing the proximal end of the inner tubular portion (80) to the hypotube (66) with a single seal adjacent the bonding region (74) as shown in Figure 2. Figure 2 also shows an inflation lumen (62 and 104) which extends through the proximal and intermediate tubular portions of the hypotube and through the annular space between the inner and outer tubular bodies into the interior of a balloon (26). The proximal collar (36) and the distal collar (40) of the balloon are affixed to the inner and outer tubular bodies. In lines 26-30 of column 10, Keith teaches the hypotube as being a single tubular shaft. With regards to claim 5, the longitudinal portion of the hypotube is shallower in the proximal direction and deeper in the distal direction as shown at 68B in Figure 5.

Keith discloses the balloon catheter substantially as claimed. However, Keith is silent on the distal portion of the hypotube having an arcuate non-tubular cross-section. In Figures 1. and 9, Happ et al show a balloon catheter having a hypotube (94), an inner

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tubular body (61) and an outer tubular body (58). The hypotube (94) has a proximal tubular portion (adjacent to 97), an intermediate tubular portion (169), and a distal portion (115) with an arcuate non-tubular cross-section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the distal portion of the hypotube of Keith with a non-tubular cross-section as taught by Happ et al as a non-tubular cross-section would lower the overall profile of the catheter and provide increased flexibility, thus enabling the catheter to be more easily inserted through the narrow passageways of a patient's body. Providing the distal portion (74B) of the hypotube of Keith with the non-tubular cross-section as taught by Happ et al would result in the catheter of Keith being structured such that the proximal ends of the inner and the outer tubular bodies would be sealed to the hypotube at a point defined proximal to a transition between the intermediate and the distal portions of the hypotube.

Even though Keith teaches using a balloon catheter in angioplasty procedures, Keith does not specifically teach the catheter having a stent crimped around the balloon. In lines 34-59 of column 1, Happ et al teach that it is well known to provide a stent around the balloon such that the stent may be left in place in the artery to keep a stenosed vessel open. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon catheter of Keith with a stent as taught by Happ et al as both Keith and Happ et al disclose using balloon catheters for angioplasty procedures and Happ et al teach mounting a stent on a balloon catheter which can then be deployed to repair a vessel.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keith and Happ et al as applied to claim 6 above, and further in view of Ressemann et al (U.S. Patent No. 5,425,711). Even though Keith teaches that it is desirable to provide a transition in flexibility between the tubular portions of the hypotube to the inner and outer tubular bodies, Keith does not teach a tapering portion between the proximal cylindrical portion and the indented intermediate portion. In Figure 5, Ressemann et al show a rapid-exchange balloon catheter with a stainless steel hypotube (23) having a tapering portion between an proximal cylindrical portion (32) and an indented intermediate portion (68) and teach that it is desirable for a catheter to have a relatively stiff proximal portion and a relatively flexible distal portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Keith to include a tapering portion between the proximal cylindrical portion and the indented intermediate portion as taught by Ressemann et al to provide more flexibility to the catheter thus allowing it to be more easily guided to a desired body location.

#### ***Response to Arguments***

5. Applicant's arguments filed May 25 2007 have been fully considered but they are not persuasive.

As to Applicant's arguments in the first paragraph of page 8, Keith does show the distal portion of the hypotube with an arcuate cross-section (72B) that extends into the outer tubular body. Furthermore, in lines 37-65 of column 8, Keith teaches that the intermediate tubular portion and the distal portion of the hypotube provide a transition in

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flexibility between the tubular portions of the hypotube to the inner and outer tubular bodies as there is a relatively sharp transition in flexibility or stiffness from the metallic sections of the hypotube to the more flexible intermediate sleeve section (24) which includes the inner body (80B) and the outer body (83B).

As to Applicant's arguments in the third paragraph of page 8, providing the distal portion (74B) of the hypotube of Keith with the non-tubular cross-section as taught by Happ et al would result in the catheter of Keith being structured such that the proximal ends of the inner and the outer tubular bodies would be sealed to the hypotube at a point defined proximal to a transition between the intermediate and the distal portions of the hypotube. In Figure 5 of Keith, it would be the section of the distal portion (74B) just distal of the point indicated by reference character 74B that would be modified to have a non-tubular cross-section. Therefore, the section of the distal portion (74B) just proximal of the point indicated by reference character 74B would be a transition between the intermediate portion and the distal portion of the hypotube, and the proximal ends of the inner and the outer tubular bodies would be sealed to the hypotube at a point defined proximal to this transition between the intermediate and the distal portions of the hypotube.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*BM*

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KEVIN C. SIMONS  
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*Kevin C. Simons*